

## 5.2 – APPENDIX B: FEES RATES AND FEE PAYING SUBMISSION TRENDS

### GDUFA Fee History

GDUFA directs FDA to collect revenue from four fee categories: ANDAs in the backlog as of October 1, 2012; DMFs; facilities, and applications (ANDA and PAS). This requires FDA to establish user fee rates by fee category, application type, location and business operation as specified in the statute. FDA published the following fee rates based on statutory target revenues and estimates of fee-paying submissions.

**TABLE 9: TRENDS IN APPLICATION, DMF, AND FACILITY FEES<sup>19</sup>**

| Fiscal Year | Backlog Fee | DMF Fee  | Domestic FDF Facility Fee | Foreign FDF Facility Fee | Domestic API Facility Fee | Foreign API Facility Fee | ANDA Fee | PAS Fee  |
|-------------|-------------|----------|---------------------------|--------------------------|---------------------------|--------------------------|----------|----------|
| 2013        | \$17,434    | \$21,340 | \$175,389                 | \$190,389                | \$26,458                  | \$41,458                 | \$51,520 | \$25,760 |
| 2014        | N/A         | \$31,460 | \$220,152                 | \$235,152                | \$34,515                  | \$49,515                 | \$63,860 | \$31,930 |

### GDUFA Forecasted Versus Actual Fee-Paying Submissions

Table 10 depicts FDA's estimates of fee-paying units used in the Federal Register (FR) notices for setting GDUFA fees prospectively versus the actual number of fee-paying units received each year.

**TABLE 10: TRENDS IN FORECASTED VS. ACTUAL FEE-PAYING APPLICATION, DMF, AND FACILITY FEES**

| Fiscal Year | Forecasted vs. Actual | Backlog Applications | DMFs  | Domestic FDF Facilities | Foreign FDF Facilities | Domestic API Facilities | Foreign API Facilities | Applications |
|-------------|-----------------------|----------------------|-------|-------------------------|------------------------|-------------------------|------------------------|--------------|
| 2013        | FR                    | 2,868                | 700   | 325                     | 433                    | 122                     | 763                    | 1,160        |
|             | Actual                | 2,851                | 1,808 | 280                     | 322                    | 123                     | 898                    | 1,145        |
| 2014        | FR                    | N/A                  | 583   | 315                     | 433                    | 128                     | 775                    | 1,149        |
|             | Actual                | N/A                  | 798   | 286                     | 366                    | 125                     | 689                    | 1,755        |

<sup>19</sup> FDA published FY 2014 human generic drug user fee rates on August 2, 2013, in the Federal Register <http://www.gpo.gov/fdsys/pkg/FR-2013-08-02/pdf/2013-18625.pdf>